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09/705,149	11/01/2000	William F. Swain	APF 34.20	4573

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EXAMINER

LI, BAO Q

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 04/05/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/705,149

Applicant(s)

SWAIN ET AL.

Examiner

Bao Qun Li

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 February 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 35-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1-51 are pending.

#### ***Election/Restrictions***

Applicant's election with traverse of Group III, claims 15-25 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that Groups I, II and III all contain same genomic fragment, is should be considered together. Group IV should be rejoined with Group III because it used same method to delivery the cosmid. The Applicants arguments are respectfully considered; Group IV may be rejoined with Group III since it uses same method in the future prosecution. Groups I and II is rejoined together for the prosecution on the merits, but they are not rejoined with Group III and IV because they are not drawn for using the same method as it is claimed in the group III.

Applicants further argue for rejoining the Groups V-VII with the Group III, the argument is fully considered; however, it is not persuasive because they are directed to the patentable distinctive invention for the same reason as described in the previous Office action.

Claims 15-34 are rejoined.

Applicants are reminded to cancel the claims 1-14 and 35-51 drawn to the non-elected groups.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is vague for failing to define what the cited "construct" is referred in the claim. The claim is interpreted in light of the specification; however, the specification fails to define what the definition of the construct is. Does it referred to a DNA molecule or a structurally

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different molecule that carries the DNA construct. Please clarify. This affects the dependent claims 16-34. *overcome*

Claim 15 is also unclear for recitation of a genomic DNA fragment derived or contained from one or more pathogen. Because the claimed language uses a relative term of "derived", in that the specification does not provide a standard for ascertaining the requisite degree of derivation and the term of "derivation" has many interpretation, one of ordinary skill in the art would not be reasonably apprised of the claimed invention. Does the genomic DNA fragment encode the full length of a pathogen or only the part of it? If it the only part of the pathogen, which part of the genomic DNA fragments is intended in the said claims, in addition, the open language of "one or more pathogens", fails to define what is the up-limitation of the subject that is intended in the said claim. Is 10 pathogens still intended? Therefore, the claim is considered indefinite. This affects the dependent claims 16-34. *may*

Furthermore, the claim 15 is still vague and indefinite in that the metes and bonds of "a particle-mediated transdermal delivery technique" are not defined. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Because there are several transdermal delivery advices in the art, the claim should point out which advice is intended in the said claim. This affects the dependent claims 16-34.

Still further, the claim 15 is still vague and indefinite in that the metes and bonds of "an amount sufficient" are not defined. Although the claims are interpreted in light of the specification, but specification does not teach what "an amount sufficient" is. Please clarify. This affects the dependent claims 16-34.

Claims 19 and 28 are unclear for recitation that construct comprises at least one pathogen. Since there is no given upper limitation of the pathogen in the said claim, is 100 pathogen intended? Therefore, the claim is considered as indefinite. Furthermore, claims 19 and 28 recite the limitation "the pathogen" in claims 17 and 26. There is insufficient antecedent basis for this limitation in claims 17 and 26, because claims 17 and 26 are directed to a plasmid or a cosmid, there is no pathogen cited in the claims. Please amend the claims to the correct dependency of a claim. This affects the dependent claims 19 and 29-30.

Claims 21 and 30 are rejected for recitation of “more than one virus”, which fails to define what is the up-limitation of the intended composition is. Is 10 viruses are intended?

Claims 22 and 31 are vague and indefinite in that the metes and bounds of the cited “a density sufficient” are not defined. The claim is interpreted in light of the specification; however, the specification fails to teach what “the sufficient density” is intended in the said claim. This affects the dependent claim 23.

Claims 23 and 32 are vague and indefinite in that the metes and bounds of “a metal” are not defined. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Because there are many metal in the art, the claim should point out which metal is intended in the said claim.

#### ***Claim Rejections - 35 USC § 112***

Claims 15-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for using a DNA-coated gold particle which carrying only one antigen of a HSV glycoprotein D to induce an immune response in animal, does not reasonably provide enablement for a method for using a DNA-coated gold particle which carrying more than one antigen from more than one pathogenic viruses to induce an immune response in animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In the instant case, the Application only present that administering the DNA-coated gold particle in which the plasmid only encodes one HSV antigen gD to induce a immune response in a mouse model.

However, the Application is deficient for teaching other DNA-coated gold particle carrying more than one antigen derived for more than one pathogenic virus that are introduced into an animal model and induce an immune response.

The specification does not teach how to select other antigen from any or all pathogenic virus.

The specification fails to teach how to construct a plasmid which carrying more than one antigens derived form more than one pathogens.

The construction of a plasmid carrying multiple antigen derived form multiple pathogen required a specific structural design in order to get all of the antigens inserted having proper expressions.

Without a proper adequate teaching, it is very unpredictable whether a DNA-coated gold plasmid carrying multiple antigens derived from multiple pathogenic viruses can induce an immune response.

Accordingly, an undue experimentation would be required for a skill artisan to make and use the full scope of the invention.

Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

### ***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 15, 17-19, 22-28, 31-34 are rejected under 35 U.S.C. 102(a) as being anticipated by Barry et al. (WO 99/31262).

Barry et al. disclose a method for delivering nucleic acid molecule into a mammal comprising the step of providing said nucleic acid molecule formulated with a trasfecting agent through and/or to the skin of said mammal by use a needle-free device configured and arranged to cause aerosol delivery of said nucleic acid molecule through and/or to the skin of said mammal by a special DNA vaccine delivery advice. The said nucleic acid sequence encodes an antigenic protein including viral antigen, such as HBV core antigen and is packaged as a gold particle. They disclose that the method results in an antibody response (See claims 1-79). Therefore, the claimed invention is anticipated by the cited reference.

Claims 15-19, 22-25 and 31-34 are rejected under 35 U.S.C. 102(a) as being anticipated by Braun et al. (Virology, 1999, Vol. 265, pp. 46-45).

Braun et al. disclose a method for delivering a gold particle-mediated DNA immunization, wherein the DNA sequence encodes a glycoprotein D of the Bovine herpesvirus-1 antigen and it is expressed under a eukaryotic control element. The particles have a diameter about 1- to 3-  $\mu\text{m}$  in ranges. All of the animals were immunized 10 shots of 1.25  $\mu\text{g}$  of DNA/0.25 mg of oil by using a special gene gun-mediated delivery system to induce an enhanced antigen specific immune response against a glycoprotein gD of bovine herpesvirus (See entire document). Therefore, the claimed invention is anticipated by the cited reference.

Claims 15, 17-19, 22-28, 31-34 are rejected under 35 U.S.C. 102(a) as being anticipated by Tacket et al. (Vaccine 1999, Vol. 17, pp. 2826-2829).

Tacket et al. disclose a method for delivering a gold particle-mediated DNA immunization, wherein the DNA sequence encodes a hepatitis-B surface antigen (HBsAg) carried by a plasmid DNA under the transcriptional control of a heterologous CMV promoter. The DNA-coated microscopic gold particle is delivered by the Powderjet XR1 particle acceleration device onto the skin of the human volunteers on day 0 and 56 to induce a booster response against HBsAg (See entire document). Therefore, the claimed invention is anticipated by the cited reference.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15, 17-19, 22-28, 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Lodmell et al. (Vaccine 1998, Vol. 16, pp. 115-118).

Lodmell et al. disclose a method for using a gene gun for delivering a particle-mediated vaccine comprising a plasmid DNA encoding a glycoprotein (G) gene of rabies virus packaged as a 0.93 or 2.6  $\mu\text{m}$  gold powder. As low as 2  $\mu\text{g}$  of DNA plasmid-coated gold beads was delivery into the abdominal epidermis of mice by using Accell®-gene delivery system and boosted after 90 days of the initial immunization to produce a long term protective immunity against rabies virus infection. (See entire document, especially section of materials and methods, section of results and discussion as well as Figures 1 and table 1). Therefore, the claimed invention is anticipated by the cited reference.

Claims 15, 17-19, 22-28, 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Haynes et al. (AIDS Research and Human Retroviruses 1994, Vol. 10, pp. S43-S45).

Haynes et al. disclose a method for using the Accell® particle-mediated gene delivery technology for delivering a DNA vaccine, wherein the plasmid DNA-coated gold microparticles encodes the HIV-gp160 and gp120 expression construct. The delivery of  $5 \times 10^7$  microsized gold particle into abdominal skin resulted in de novo antigen expression in epidermal cells that stimulated the induction of antigen-specific humoral and cytotoxic cellular immune response (See entire document). Therefore, the claimed invention is anticipated by the cited prior art.

Claims 15, 17-19, 22-28, 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Webster et al. (Vaccine 1994, Vol. 12, pp. 1495-1498).

Webster et al. disclose a method for using the Accell electric discharge particle bombardment device for delivering a DNA vaccine, wherein the plasmid DNA is constructed with cytokine IL-2 pBC12/CMV/IL-2) is coated gold beads in 1-3  $\mu\text{m}$  or 0.95  $\mu\text{m}$  size, which expresses an influenza virus haemagglutinin and IL-2 expression and provide a complete protection immunity against the homologous influenza virus infection (See entire document). Therefore, the claimed invention is anticipated by the cited prior art.

Claims 15, 17-19, 22-28, 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Macklin et al. (Journal of Virology 1998, Vol. 72, pp. 1491-1496).



Macklin et al. disclose a method for using the Accell electric discharge particle bombardment device for delivering a DNA-coated gold particle carrying the DNA sequence encoding the influenza virus HA protein to induce an immune response. They teach that the antigen is carried by a 1- to 3-  $\mu\text{m}$  plasmid DNA gold particles and expressed under heterologous CMV promoter. They also teach that the vaccination procedure is carried out by prime injection and boost immunization with a cartridge that contains 0.5 mg of gold particles coated with 1.25  $\mu\text{g}$  of plasmid through epidermis to produce a protective immune response in pigs (See entire document). Therefore, the claimed invention is anticipated by the cited reference.

Claims 15, 17-19, 22-28, 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Fynan et al. (P.N.A.S. U.S.A. 1993, Vol. 90, pp. 11478-11482).

Fynne et al. disclose a method for using the Accell instrument for delivering a DNA-coated gold particle carrying the DNA sequence encoding the influenza virus HA1 or 7 protein onto the skin of tested animals to induce an immune response. They teach that the antigen is carried by a plasmid DNA under a heterologous promoter CMV and it is affixed to a 0.95  $\mu\text{m}$  size gold particle to produce a 95% protective immune response (See entire document). Therefore, the claimed invention is anticipated by the cited reference.

### ***Claim Rejections - 35 USC § 102***

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 15, 17-19, 22-28, 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnston et al. (US Patent 6,1694,389B1).

Johnston et al. disclose a method for transferring a gene to vertebrate cells comprising the injecting a microprojectile into a host to induce a protective immunity (See claims 1-11), wherein the microprojectile is a DNA-coated particle carrying a recombinant construct of a gene and a regulatory element. The construct may take any suitable form, such as plasmid, a genomic viral DNA sequence, particularly the plasmids are currently preferred. Johnston et al. teach that any microprojectile acceleration cell transformation apparatus can be used in practicing the invention. They also teach that of microprojectile (i.e. microparticle) used in carrying out the invention may be formed from any material having sufficient density and cohesiveness to be propelled into cells of the tissue being transformed. Metallic particle are currently preferred (line 4-45 on col. 6). They teach that a gold particles ranging in diameter from about one micrometer to about three micrometers are preferred (See lines 46-64 on col. 6). Johnston et al. teach that variety of antigen, protein, peptide, which produce an immune response are suitable for using the claimed method (See lines 66 on col. 4 through line 37 on col. 5). Johnston et al. all teach that variety of the regulatory elements suitable for controlling the transcription of the inserted gene in the DNA plasmid (See lines 38-64 in col. 5). Therefore, the claimed invention is anticipated by the cited reference.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston et al. (US Patent 6,1694,389B1), Braun et al. (Virology 1999, Vol. 265, pp. 46-56), Stanberry et

al. (J. Infect. Dis. 1987, Vol. 155, pp. 156-163), Pertmer et al. (Vaccine 1995, Vol. 15, pp. 1427-1430) and Barry et al. Vaccine 1997, Vol. 15, pp. 788-791).

The present invention is drawn to a method for inducing an immune response by injecting a DNA-coated gold particle in animal by a special particle-mediated transdermal delivery technique, wherein the DNA is a plasmid or cosmid DNA vector encodes one or more pathogenic virus antigen, such as HSV-2 glycoprotein D (HSV-1 gD-antigen) and is not driven by a heterologous promoter. The gold core carrier has an average diameter of about 0.5 to 5  $\mu\text{m}$  and the genomic fragment DNA is about 5kb to 25 kb in size.

Johnston et al. disclose a method for transferring a gene to vertebrate cells comprising the injecting a microprojectiles into a host to induce an immune response (See claims 1-11), wherein the microprojectile is a DNA-coated gold particle carrying a recombinant construct of a gene and a regulatory element. The construct may take any suitable form, such as plasmid, a genomic viral DNA sequence, particularly the plasmids are currently preferred. Johnston et al. teach that any microprojectile acceleration cell transformation apparatus can be used in practicing the invention. They also teach that of microprojectile (i.e. microparticle) used in carrying out the invention may be formed from any material having sufficient density and cohesiveness to be propelled into cells of the tissue being transformed. Metallic particle, such as gold is currently preferred (line 4-45 on col. 6). They teach that a gold particles ranging in diameter from about one micrometer to about three micrometers are preferred (See lines 46-64 on col. 6). Johnston et al. teach that variety of antigen, protein, peptide, which produce an immune response are suitable for using the claimed method (See lines 66 on col. 4 through line 37 on col. 5). Johnston et al. all teach that variety of the regulatory elements suitable for controlling the transcription of the inserted gene in the DNA plasmid (See lines 38-64 in col. 5). Johnston et al. differ in that they do not teach particularly the use of herpes virus antigens or antigens from two different viruses.

Braun et al. disclose a method for delivering a gold particle-mediated DNA immunization, wherein the DNA sequence encodes a glycoprotein D of the Bovine herpesvirus-1 antigen and ranges from 1- to 3-  $\mu\text{m}$  gold beads. All of the animals were immunized 10 shots of

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1.25 µg of DNA/0.25 mg of old by using a special gene gun-mediated delivery system to induce an enhanced an antigen specific immune response against a glycoprotein of BHA-1 (See entire document). Braun et al. differs in that they teach that the DNA sequence encodes a herpesvirus glycoprotein D antigen is from the bovine origin rather than a human origin as claimed in the instant Application. However, they demonstrate that cattle were immunized by the gene gun with a plasmid expressing a truncated, secreted form of bovine herpesvirus-1 glycoprotein D, the cattle got a significantly serum antibody response, antigen specific proliferation, and interferon- $\lambda$  secretion by peripheral blood lymphocytes. Their immune response were found to be of long duration and sufficient magnitude to protect cattle against challenge with bovine herpesvirus-1 (Abstract) and they concluded that the results reported here illustrate how gene gun-based immunization with a DNA vaccine can induce both humoral and cellular response in large animal and the data present in the paper have a significant implications not only for the potential development of DNA vaccine for cattle but also for the application of gene gun-mediated delivery to large animal in general.

Stanberry et al. demonstrate that the administration of a mixture of HSV-2 glycoprotein B and D derived from infected tissue cultures in a guinea pig model reduce significantly the frequency and severity of subsequent herpetic recurrences. They concluded that HSV glycoproteins may be useful as immunotherapeutic agents for controlling recurrent HSV infection in humans (Abstract). The disclosure of Stanberry et al. differs from that of the instant Application since they are not use the DNA-coated gold particle to delivery the antigen to see the immune response.

However, the use of a gene gun for delivering a DNA-coated gold particles carrying an pathogenic antigen onto the skin of a mammal to induce an immune response is so well known in the art as evidenced by so many prior art cited supra, such as Johnston et al. and Braun et al. which all disclose a very detailed experimental designs and approaches. Because the method has been recognized highly in the art as a time and labor saving in producing antibodies with 100-fold less to 5000-fold less DNA requirements and more reproducible in effect as described by Pertmer et al. (Abstract) and Barry et al. (Abstract), in view of a demand for protecting the congenital infection of human herpes simplex virus in the art, it would have been obvious for an

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ordinary artisan to be motivated by combining the teaching from Johnston et al. and Braun et al. in further view of the teaching by Stanberry et al. to make a DNA-coated gold particle as taught by Johnston et al. and Braun et al. wherein the DNA plasmid can be designed to carry one or two herpes simplex viral antigen, such as the glycoprotein gB and gD as disclosed by Stanberry and test the immune response by delivering it as a DNA-coated gold particle with the commercial gene gun delivery advice onto the skin of a tested mammal to induce an immune response with highly expected success.

Because the method for using the gene gun for delivering a DNA-coated particle loaded with a DNA plasmid for inducing an immune response is well established method with more efficient effect and economic beneficial, the modification of the plasmid carrying more than one antigens either from same pathogenic virus or from different pathogenic viruses is generally recognized as being within the level of the ordinary skill in the art, since most available antigens used in the art are all well characterized too unless Applicant point out the structures of the antigens used for the claimed invention are so unique in that only the DNA-coated gold particle can be used for the carrier to induce an immune response. See *In re Rose*, 105 USPQ 237 (CCPA 1995) because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the workable ranges involves only routine skill in the art, *In re Aller*, 105, USPQ 233.

Hence, the claimed invention is as whole a prime facie case obvious without any unexpected result.

### ***Conclusion***

No claimed are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

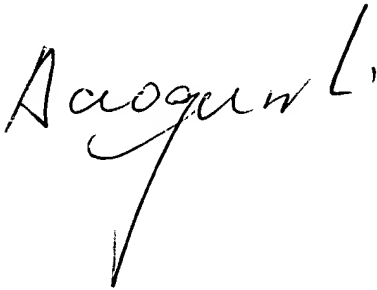

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

April 4, 2002

A handwritten signature in cursive script, appearing to read "Bao Qun Li", with a large checkmark-like flourish at the bottom.A handwritten signature in cursive script, appearing to read "Ali R. Salimi", positioned above a printed name and title.

ALI R. SALIMI  
PRIMARY EXAMINER